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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/708,249

02/19/2004

Walter Uebelacker

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EXAMINER

KHOLDEBARIN, IMAN K

ART UNIT

PAPER NUMBER

3737

MAIL DATE

DELIVERY MODE

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/708,249

Applicant(s)

UEBELACKER, WALTER

Examiner

I Kenneth Kholdebarin

Art Unit

3737

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 02/26/2004.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_.

## DETAILED ACTION

### *Claim Rejections - 35 USC § 101*

1. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 1-27 are rejected under 35 U.S.C. 101 because the disclosed invention is inoperative and therefore lacks utility. Based on the specification disclosed [0012 and 0013] the task of the present invention is to optimized the interaction of the shock wave with the tissue of a subject being treated so as to achieve the best clinical result. Applicant disclosed that this task is accomplished by using high-energy shock waves are generated by electro hydraulic, electro magnetic or piezoelectric means, but not focused into a focal point. Instead, the shock wave is reflected or refracted in such a way that a plane wave or flat wave is emitted from the source. Furthermore applicant discloses that the structure of the present apparatus comprises of a reflector housing, a parabolic reflector disposed in the hosing and energy source [0015, line 1-4]. And, in an embodiment, the energy source may have a propagation point centered approximately at the focal point of the parabolic reflector [0016]. In view of one ordinary skill in the art at time of this invention was made studies show that reflection of the waves emitted from the energy source based on the location disclosed by the applicant will not result in a plane wave or flat wave format. Please see the following reference.

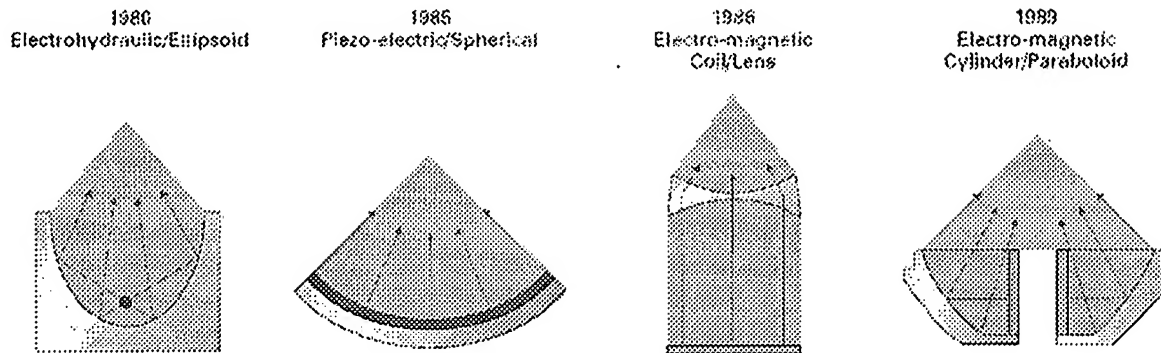


Fig. 3. A schematic drawing of the various shock-wave sources currently in clinical use.

#### Reference:

*BJU International* (2002), 90, 507-511

doi:10.1046/j.1464-4096.2002.02961.x

## A comparative review of extracorporeal shock wave generation

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### *Claim Rejections - 35 USC § 112*

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claim 1-27 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. It is not clear to understand based

on Fig. 1, Fig. 2 and the specification disclosed on the application under review, how to generate plane wave or flat wave while the energy source of (electro hydraulic, electro magnetic or piezoelectric) is disposed within the reflector and centered approximately at a focal point of the parabolic reflector.

*Claim Rejections - 35 USC § 102*

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

5. Claim 1, 2, 4-7, 13, 17-19 and rejected under 35 U.S.C. 102(e) as being anticipated by Wilbert.

Re Claim 1, 4, 17, 18: Wilbert discloses a therapeutic shock wave device and method comprising a reflector housing, a parabolic reflector and an energy source and coupling member (See Paragraph 1, 3 and Fig. 3).

Re Claim 2: Wilbert disclose that the shock wave having a power density (shock wave energy or Energy flux density) level to produce a tissue reaction (See paragraph 9 and 10).

Re Claim 5: Wilbert disclose that the focal point to be 5mm zone. For practical reasons related to location devices the 5 mm zone is defined as an additional zone of interest inside which the pressure is constant, (See Paragraph 8).

Re Claim 6 and 7: Wilbert disclose that the energy source is an electro-hydraulic source, (See paragraph 13, "titled principle of shock wave generation" and Fig.3a).

Re Claim 17: Wilber discloses that method and the device of shock wave could be used for treating physiological repair e.g. urinary or biliary tract calculi. (See Paragraph 2)

6. Claim 13, 18 and 19 rejected under 35 U.S.C. 102(e) as being anticipated by Candy (US 2004/0059265).

Re Claim 13 and 18: Candy discloses a shock wave device and method that generates planar shock wave and propagates the planar shock wave towards the subject, (Fig. 10, and paragraph [0189] and [0209]).

Re Claim 19: Candy disclose that as result of emitting the shock (step 104) dynamically focusing the acoustical energy on the mass in the substance utilizing time reversal creates mechanical disruption of cell membranes through cavitations and cell death. Furthermore as a result if

acoustic waves Chemical reactions generally run faster at higher temperature and diffusion of reagents should also be improved (See paragraph [0154] and [0031]).

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 3 and 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over applicant own admitted prior art.

Re Claim 3 and 15: The applicant discloses that the shock wave device and method has at reach a certain power density in order to produce a tissue reaction, (see paragraph [0009]).

Wilbert also discloses that Energy flux density is defined as a certain amount of energy passing through a defined area (given in  $\text{mJ/mm}^2$ ), See Fig. 2).

9. Claims 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilbert in view of Delmenico (US 5,658,239)

Wilbert teaches the apparatus and method where the shock wave comprises the energy source but fails to disclose or fairly suggest the structure of the source comprises a pair of electrode tips connected to a capacitor.

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Delmenico teaches Shock waves generated by the underwater discharge of a capacitor can be reliably reproduced wherein the electro-hydraulic method, electricity is discharged into water across a gap between two electrodes, (See paragraph 19).

Therefore in view of Delmenico, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have two electrodes within the structure of the energy source and a capacitor, in order to reproduce the energy and generates future shock waves.

10. Claims 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilbert in view of Eizenhoefer (US 5,119,801)

Wilbert teaches the use of fluid and water in the shock wave device but Wilber fails to disclose the membrane separates the cavity containing the water.

Eizenhoefer teaches one will use preferably a metal membrane on the front (inwardly pointing) ends of the piezoelectric elements, being as far as impedance is concerned matched to these elements and providing physical separation between the isolating fluid and any coupler liquid on the inside of the spherically shaped space of the membrane, (See Col. 1, line 45-55).

Eizenhoefer furthermore disclose that the fluid could be water or gel. (See Col.2, line 10-15).

Therefore in view of Eizenhoefer, it would have been obvious to one of ordinary skill in the art at the time of the invention was made to have a membrane to isolate the fluid which provides in fact a drastic increase in the strength against voltage breakthrough of the device.

11. Claims 14 and 23-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilbert in view of Eizenhoefer (US 5,119,801) further in view of Delenico (US 5,658,239).



Re Claim 14, 16 and 23-27: Wilbert teaches a method and apparatus using the shock wave device having a parabolic reflector and energy source but he fails to suggest the energy source made out of electrode and membrane.

Delmenico teaches that the energy source to comprise of electrode tip and capacitor but fails to suggest the shock wave source to have a membrane disposed across a cavity.

Eizenhofer teaches the shock wave device and method to have a membrane disposed across a cavity in conjunction with the parabolic reflector to contain fluid.

Therefore in view of Delmenico, and further Eizenhofer it would have been obvious to one of ordinary skill in the art at the time the invention was made replace the energy source comprising two electrode with the energy source introduced by Wilbert and further modified the shock wave with a membrane taught by Eizengoefer in order to generate acoustic wave form for therapeutic device.

12. Claims 20-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Candy in view of Walbert (BJU international (2002), 90, 507-511)

Candy teaches the method of therapeutic treatment comprising generating a planar shock wave and coupling the planar shock wave to the tissue to be treated. But Candy fails to suggest the use of hydraulic, electromagnetic or piezoelectric.

Walbert teaches method of using electro-hydraulic, electromagnetic or piezoelectric and reflecting the shockwave from a parabolic reflector, (See Fig. 3).

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Walbert further teaches to have a sufficient power density to cause the tissue to be activated but he doesn't suggest for generating an immune response. But candy discloses the use of acoustic energy will increase the heating of the selected tissue region and further Hyperthermia in the 40-46.degree. C. range can significantly enhance clinical responses to radiation therapy and has the potential for enhancing other therapies, such as chemotherapy, immuno-therapy and gene therapy. (See paragraph [0147]).

Therefore in view of Walbert, it would have been obvious to one of ordinary skill in the art at the time of the invention was made to use electro-hydraulic, electromagnetic or piezoelectric sources within the shock wave device to increase the reaction of the tissue due the acoustic sounds wave and possibly use that therapies for chemotherapy or immuno-therapies.

### *Conclusion*

13. The prior art made of record and not relied upon is considered pertinent to applicants disclosure. Discloses Candy disclosed Dynamic acoustic focusing utilizing time reversal; Filler discloses Extracorporeal shock wave lithotripsy employing non-focused, spherical-sector shock waves; Reichenberger discloses Apparatus for producing time-staggered shock waves; Visuri discloses Piezoelectric shock wave generator; and Menne discloses Medical instrument for treating biological tissue and method for transmitting pressure waves.


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14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to I Kenneth Kholdebarin whose telephone number is 571-270-1347. The examiner can normally be reached on M-F 8 AM- 4 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Iman Kenneth Kholdebarin/  
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04/25/2007

  
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